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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/577,264

05/22/2000

John S. Patton

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05/24/2006

NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,264

Applicant(s)

PATTON, JOHN S.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 21, 24, 26, 28-34, 36, 38, 39, 41, 46-68 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56, 57, 60, 63-65 and 67 is/are rejected.
- 7) ☒ Claim(s) 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims:

Claims withdrawn from consideration are 20,21,24,26,28-34,36,38,39,41,46-55,58,59,61,62 and 68.

Pursuant to the directives of the response filed 3/13/06, claim 59 has been amended, and claims 60-68 added. Claims 20, 21, 24, 26, 28-34, 36, 38, 39, 41, 46-68 are now pending.

Claims 20, 21, 24, 26, 28-34, 36, 38, 39, 41, 46-55, 58, 59 are withdrawn pursuant to the restriction; claims 61, 62 & 68 are withdrawn because they do not encompass the elected species. Claims 56, 57, 60, 63-67 are examined in this Office action.

Applicants' arguments filed 3/13/06 have been considered and found not persuasive.

Claims 56, 57, 60, 63, 64, 67 are rejected for the reasons given hereinbelow; claim 66 is objected to because of its dependence on a rejected claim.



Claims 56, 57, 60, 63-65, 67 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 recites that the composition in question "comprises" a powder. At the same time, claim 56, upon which claim 65 depends, recites that the composition in question "consists essentially of" the indicated ingredients. Applicants have argued that the term "consists essentially of" means that the composition is limited to whatever specific ingredients are recited. According to this view, claim 65 is not properly subgeneric to

claim 56, since claim 65 would permit numerous constituents to be present which are not (according to applicants) permitted by claim 56.

Claim 56 encompasses treatment of a person who is showing no signs of osteoporosis, but for whom there is a suspicion that she is vulnerable to the same. What would be the manifestations of a successful treatment for a patient who has shown no signs of osteoporosis at the time that the treatment is initiated...? In response to the foregoing, applicants have attempted to commingle the issues of treating a patient who is showing symptoms of osteoporosis, and one who is not. However, these are entirely separate embodiments. The examiner has not previously, and does not now assert that a claim drawn to treating osteoporosis is indefinite, if that claim also makes clear that symptoms of the disease are present at the time that treatment is initiated. Instead, the issue is that the claim is also drawn to a method of treating a patient who applicants may believe are at risk of developing osteoporosis, but which patient is not, at the same time, exhibiting any symptoms of the disease. Applicants have further implied that a 112-2nd paragraph rejection is overcome if an applicant makes an admission as to what might constitute infringement at some point in the future. The examiner, however, does not agree that such an admission overcomes the rejection. Further, it is not at all clear what would constitute infringement, or how it would be determined.

PTH has been asserted (by various inventors) to be useful for treating other diseases/disorders such as Paget's disease, skin disorders, acne, and alopecia; it has also

been asserted to be useful for inducing differentiation of tumor cells, and for modulating immune responses. If a person were attempting to treat one of the foregoing diseases, or effect one of the foregoing responses (differentiation or modulation), would she be infringing on the claim?

Suppose that there are two female subjects, subject #1 and subject #2. Subject #1 has a family history of osteoporosis, and genetic analysis indicates that she also has a predisposition towards the disease, but she shows no symptoms. Subject #2 has no family history of osteoporosis, and genetic analysis using the methods available in 1992, or even in 2006, fail to indicate any predisposition towards the disease. Suppose that, for one reason or another, subject #2 decided to inhale some PTH despite knowing the results of the genetic analysis. Perhaps she mistakenly believed she was at risk, even though she really was not at risk. Is it applicants' contention that her action would fall within the scope of the claims? And suppose that subject #2 did not know whether she was "at risk" of osteoporosis. Would that change the analysis if she were to inhale the PTH...? Next, consider subject #1. And suppose that, according to the genetic methods available in the year 1992, there was no evidence of a predisposition towards osteoporosis. But suppose also that, using the genetic methods available in the year 2006 or perhaps the year 2010, there was compelling evidence that osteoporosis was imminent. Presumably applicants would argue that if subject #1 inhaled PTH in the year 2006, her action would fall within the scope of the claims. But what about inhaling in the year 1992...?

What are the criteria for deciding who is “at risk”, and what are the manifestations of a successful treatment if the subject showed no symptoms to begin with?



The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 56, 57, 60, 63, 64, 65, 67 are rejected under 35 U.S.C. §103 as being unpatentable over Wang (USP 5,011,678) in view of Neer (USP 4,698,328).

As indicated previously, Wang discloses (col 7, line 17) that PTH can be administered in aerosol form. There are also several references to fluorocarbon, chlorofluorocarbon and hydrocarbon propellants. Wang does not disclose fragments of PTH. Neer discloses (col 4, line 50+) the use of PTH(1-34) and advantages associated therewith. Thus, it would have been obvious to treat osteoporosis by inhaling PTH(1-34).

In response to the foregoing, applicants have argued that the term “consisting essentially of” is effective to exclude all compounds other than the PTH peptide, the bulking agent and the propellant. However, applicants are not correct.

As it happens, the steroids mentioned in Wang are not “essential” to the composition. Applicants have also implied that in considering the teachings of a patent document, one should consider only the examples, and disregard all other teachings. However, applicants are not correct about this proposition.

The rejection is maintained.



Claims 56, 57, 60, 63, 64, 65, 67 are rejected under 35 U.S.C. §103 as being unpatentable over Wang (USP 5,011,678) in view of Morita (USP 4,656,250).

As indicated previously, Morita discloses that the peptide [Nle⁸, Nle¹⁸, Tyr³⁴] PTH(1-34) has advantages over PTH(1-34). Morita does not disclose administration by inhalation; however, this is disclosed in Wang. Thus, it would have been obvious to treat osteoporosis by inhaling the PTH(1-34) analog that is disclosed in Morita.

In response to the foregoing, applicants have argued that the term “consisting essentially of” is effective to exclude all compounds other than the PTH peptide, the bulking agent and the propellant. However, applicants are not correct.

As it happens, the steroids mentioned in Wang are not “essential” to the composition. Applicants have also implied that in considering the teachings of a patent document, one

should consider only the examples, and disregard all other teachings. However, applicants are not correct about this proposition.

The rejection is maintained.



THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

No claim is allowed.



DAVID LUKTON, PH.D.
PRIMARY EXAMINER

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.